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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,633	04/20/2001	Gregory A. Demopulos	OMER117356	2163

26389 7590 07/08/2005

CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC
1420 FIFTH AVENUE
SUITE 2800
SEATTLE, WA 98101-2347

EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,633	DEMOPULOS ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,22 and 25-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22 and 25-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/13/05*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

1. The finality of the last office action has been withdrawn due to new rejections.

Claims Status

2. Claims 20, 22 and 25-38 are pending in the instant application. Claims 39, 41 and 44-50 have been canceled as requested by Applicant in the Paper filed June 13, 2005.

Withdrawn Objections and Rejections

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4.1 Claims 20, 22 and 25-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5, 7-10 of U.S. Patent No. 5,800,385, claims 1-4, 6, 8-15 of U.S. Patent No. 5,858,017, claims 1-10 of U.S. Patent No. 5,860,950 and

claims 1-11 of U.S. Patent No. 6,261,279. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering a solution comprising at least one tumor necrosis factor soluble receptor, and the claims of U.S. Patent No. 5,800,385, U.S. Patent No. 5,858,017, U.S. Patent No. 5,860,950 and U.S. Patent No. 6,261,279 are drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering a solution comprising a plurality of pain/inflammation inhibitory agents.

Fahey, U.S. Patent No. 5,145,676, teaches at column 2, lines 35-40, that TNF levels appear to peak on the first day of wound healing.

Van Zee et al. (Proc. Natl. Acad. Sci., Vol. 89, pp. 4845-4849, June 1992) teaches that tumor necrosis factor soluble receptors can protect against experimental and clinical inflammation by binding excessive TNFα.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to preemptively inhibit pain and inflammation at a wound during a surgical procedure comprising delivering a solution comprising at least one tumor necrosis factor soluble receptor, since tumor necrosis factor was well known in the art to cause inflammation and was increased at wound sites within a day as taught by Fahey et al., and tumor necrosis factor inhibitors such as soluble receptors were also well known in the art and known to protect against inflammation, as taught by Van Zee et al. The would be a reasonable expectation of success, since soluble TNF receptors had been shown in the art to successfully bind to and ameliorate the effects of TNF.

4.2 Claims 20, 22, 25-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/138,192, claim 1 of copending Application No. 10/138,193, claims 1-8 of copending Application No. 10/288,997, claim 1 of copending Application No. 10/630,626 and claims 1-5 of copending Application No. 10/674,290. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention of the instant application is drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to a wound during a surgical procedure a solution comprising at least one tumor necrosis factor soluble receptor, applied locally and perioperatively to the surgical site, and the claims of the other copending applications are drawn to methods of inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to a wound during a surgical procedure a solution comprising a number of anti-inflammatory or pain reducing compounds.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to preemptively inhibit pain and inflammation at a wound during a surgical procedure comprising delivering a solution comprising at least one tumor necrosis factor soluble receptor, since tumor necrosis factor was well known in the art to cause inflammation and was increased at wound sites within a day as taught by Fahey et al., and tumor necrosis factor inhibitors such as soluble receptors were also well known in the art and known to protect against inflammation, as taught by Van Zee et al. The would be a reasonable expectation of success, since soluble TNF receptors had been shown in the art to successfully bind to and ameliorate the effects of TNF.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara

Eileen B. O'Hara, Ph.D.

EILEEN B. O'HARA
PATENT EXAMINER

Patent Examiner